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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,192	03/25/2004	Manne Satyanarayana Reddy	Bulk 3.0-045	6006

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DR. REDDY'S LABORATORIES, INC.
200 SOMERSET CORPORATE BLVD
SEVENTH FLOOR,
BRIDGEWATER, NJ 08807-2862

EXAMINER	
MOORE, SUSANNA	
ART UNIT	PAPER NUMBER
1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,192	REDDY ET AL.	
	Examiner	Art Unit	
	Susanna Moore	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/8/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *35-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-21 and 32 in the response filed on January 8, 2007 is acknowledged. Applicants elected with traverse the restriction on the grounds that the restriction is improper because the inventions are neither independent nor distinct and therefore would not impose a burden on the Examiner. The traversal was persuasive in-part. Namely, Group II (claims 26-31), Group III (claims 33-34) and Group IV (claims 22- 25) will be examined together although claims 35-38, originally placed into Group II have been restricted from the other claims. Claims 35-38 are drawn to a process of making cetirizine dihydrochloride from cetirizine monohydrochloride (amorphous). Group II does not make or use the product of Group I. Thus, claims 1-34 will be examined together and claims 35-38 are withdrawn from further consideration.

Thus, the revised restriction is as follows:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-34, drawn to a crystalline form of cetirizine monohydrochloride, compositions, process of making and method of using thereof, classified in class 544, subclass 396 and class 514, subclass 255.04.

II. Claims 35-38, drawn to a process of making cetirizine dihydrochloride, classified in class 544, subclass 396 and class 514, subclass 255.04.

Inventions (I) and (II) are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, claims 35-38 are drawn to a process of making cetirizine dihydrochloride from cetirizine monohydrochloride (amorphous). The amorphous form of cetirizine monohydrochloride is neither emcompassed by claim 1, nor is it a method of using the crystalline form of cetirizine monohydrochloride. Therefore, the Group (II), process of making cetirizine dihydrochloride, is unrelated to Group (I), the crystalline form of cetirizine monohydrochloride.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants traverse the retriction requirement by stating, "Further, the requirement that the claim groups would be able to support separate patents has not even been addressed. It is stated in M.P.E.P. § 802.01: Related inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER."

To address Applicants argument, Group (I), drawn to a crystalline form of cetirizine monohydrochloride, compositions, the process of making and method of using thereof, is patentable over Group (II), a process of making cetirizine dihydrochloride. Therefore, the Examiner has addressed this requirement, which renders the restriction requirement proper.

Therefore the following restriction is **final** for the reasons provided above. Applicants may petition under 35 CFR 1.144.

Claim Objections

Claim 28 is objected to because of the following informalities: the number "26." Is found in front of the 28 for claim 28. Please remove the "26." from the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of claim 9 is drawn to a pharmaceutical composition but the claim does not recite a carrier. Is Applicant claiming a compound or composition?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Baltes et. al. (U.S. 4,525,358).

The reference teaches 2-[2-[4-[(4-chlorophenyl)phenylmethyl]-1-piperazinyl]ethoxy]-acetic acid as an antiallergic agent. See column 10, lines 55-57 and column 1, lines 62.

Applicant is claiming a composition comprising the above-mentioned compound as a particular crystalline form in a pharmaceutically acceptable carrier, e.g. water. If the polymorph is placed in any liquid pharmaceutically acceptable carrier, the compound will not retain its crystalline form, and thus, is anticipated by Baltes et. al.

The Examiner suggests the insertion of the word "solid" in front of "composition" in claims 18 and 19 to overcome the rejection.

Claims 1-17 and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Duchene et al. (US 6,255,487).

The instant Application claims a crystalline form of cetirizine monohydrochloride, the process of making said crystalline form and a method of treating allergic syndromes.

Duchene teaches a process of making cetirizine and a method of treating allergic syndromes with said compounds. See column 19, lines 17-46 for the compound and column 2, line 12.

Note the following:

a) The process of making cetirizine found in column 19, lines 17-46, shows the reaction was acidified to a pH of 4-5 to protonate the carboxylate to the acid. See line 31. The solid was then filtered, collected and acidified with concentrated HCl in acetone to afford cetirizine. Based on the second addition of concentrated HCl it is clear that the HCl salt was made in the reference. Due to the process provided in the reference, there is every reason to believe the monohydrochloride salt was formed. Note that the process is done in aqueous acetone, the same solvent mixture that Applicants use.

b) The reference is silent as to whether a crystalline solid was formed, and if so which one. The reference only states a "white solid" was formed and collected. Continuing with the above explanation, there is every reason to believe the HCl salt formed and the crystalline cetirizine monohydrochloride was formed.

The reference shows the cetirizine compound, but is silent on the particular crystallographic form. MPEP 2112 states:

"SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

In this case, the "unknown property" is the particular crystalline form. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

"A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection."

Again, the "CHARACTERISTIC" which the prior art is silent on is the crystalline form (crystalline form is considered to be in the category of chemical properties; see *Zenith Laboratories Inc. v. Bristol-Myers Squibb Co.* 30 USPQ2d 1285, 1288).

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. In every reference applied, the reference explicitly teaches exactly what the compound is. In fact, it is the opposite. In a normal inherency situation, the claim is of known structure, and the reference is of unknown structure. Here, the reverse is true, and hence the legal circumstances of inherency-in-the-prior-art do not apply. The only difference is the property about which the reference happens to be silent.

See for example *Ex parte Anderson*, 21 USPQ 2d 1241 at 1251, discussion of Rejection E. The claims had "numerical or functional values for certain properties which [the authors of the references] did not measure". The PTO presented no reasoning as to why the prior art material would have been expected to have those properties. Instead, the decision states, "There is ample

precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture." (page 1253).

In another example, certain claims of *Ex parte Raychem Corp.* 25 USPQ2d 1265 required a linearity ratio of less than 1.2. The decision notes that neither reference discloses any values of the linearity ratio. The PTO presented no reasoning as to what the ratio would be expected to be in the references. The Decision states: "However, this does not end the inquiry since, where the Patent and Trademark Office is not equipped to perform the needed testing, it is reasonable to shift the burden of proof to Raychem to establish that (1) the argued difference exists...."

And indeed, there have been a number of cases in which applicants have pointed to silence of the prior art with regard to this or that property: *In re Pearson*, 181 USPQ 641; *In re Zierden* 162 USPQ 102; *In re Lemin*, 140 USPQ 273; *Titanium Metals Corporation of America v. Banner*, 227 USPQ 773; *In re Benner,* 82 USPQ 49. Going further, if silence about properties of prior art compounds could be relied on, then one could not reject over references with no utility (see *In re Schoenwald*, 22 USPQ2d 1671), since applicants could always insert the utility into the claim as a property.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially

> identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, or 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Overcoming the rejection is very straightforward. One simply replicates the prior art procedure. If the claimed form does not appear at all in the product, or if on repetition, it sometimes does not appear in the product, then the rejection is overcome.

Claims 1-21 and 26-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Singh et. al. (WO 2004/103982 A1).

Singh teaches a crystalline form of cetirizine monohydrochloride, a process of making said crystalline cetirizine and a method of treating allergic syndromes with said compounds. See page 8, example (c) for the process, pages 9-10 for the crystalline cetirizine monohydrochloride Xray data, page 11, line 15 for the method of treating allergic conditions and page 11, line 13 for the compositions.

Based on a visual overlay of the the Xray diffraction patterns of the crystalline cetirizine monohydrochloride in the instant Application and that of the reference (see page 3/8 in the reference), followed by a comparison of the DSC data provided in both the instant Application and the reference (Applicants 186°C versus 187.7°C, see page 4/8 of the reference), the

Examiner has determined this is the same crystalline form of cetirizine monohydrochloride Applicant is claiming in the instant case.

Also the process on page 8 of the reference teaches the monohydrochloride salt in the reaction mixture and acetone is used as the polar solvent.

Furthermore, a general teaching for the compositions can be found on page 11, the third paragraph. The reference also teaches the different solid dosage forms.

Thus, claims 1-21 and 26-34 are rendered anticipated by Singh et. al.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a copy of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et. al. (WO 2004/103982 A1) as applied to claims 22 and 23 above, and further in view of Johnson et. al. (US 2002/0012700 A1) or Sunshine et. al. (US 4,829,064) or Rubin (US 2002/0099058 A1).

These claims are drawn to a particular crystalline form of cetirizine monohydrochloride in pharmaceutical compositions with additional active ingredients, i.e. pseudoephedrine, leukotriene inhibitor and an analgesic.

Singh teaches a crystalline form of cetirizine monohydrochloride in a simple composition, page 11, line 13, as discussed above.

Johnson et. al. teaches a pharmaceutically acceptable salt of cetirizine in a composition with pseudoephedrine. See page 1, paragraphs 0006, 0021 and 0022.

Thus, it would be obvious to one of ordinary skill in the art to use the crystalline form as taught by Singh et. al. in a composition with pseudoephedrine since Johnson teaches the combination of cetirizine monohydrochloride of any form and pseudoephedrine and the crystalline form of cetirizine to improve the dosage form stability.

The same argument given above can be applied to Sunshine et. al., which teaches cetirizine in a composition with a leukotriene inhibitor, or Rubin et. al., which teaches cetirizine in a composition with an analgesic.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SM

Mark L. Berch
Primary examiner
Art Unit 1624
Technology Center 1600

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SM

SM

Mark L. Berch
Primary examiner
Art Unit 1624
Technology Center 1600